

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

PHARMACEUTICAL RESOURCES, INC.	:	
and PAR PHARMACEUTICALS, INC.,	:	
	:	Civ. No. 03-3357(DRD)
Plaintiffs,	:	
	:	<b><u>OPINION</u></b>
v.	:	
	:	
ROXANE LABORATORIES, INC.	:	
	:	
Defendant.	:	
	:	

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**Debevoise, Senior District Court Judge**

Plaintiffs, Pharmaceutical Resources, Inc., and Par Pharmaceutical, Inc. (collectively, “Par”) instituted this patent infringement action against Roxane Laboratories, Inc. (“Roxane”), alleging infringement of U.S. Patent No. 6,593,318 (“the ‘318 patent”) and U.S. Patent No. 6,593,320 (“the ‘320 patent”). Roxane denied infringement and asserts that the ‘318 and ‘320 patents are invalid and unenforceable. A Markman hearing was held to determine the meaning of disputed claim terms. Markman v. Westview Instruments, Inc., 52 F. 3d 967 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996).

On May 25, 2006 the court issued an Amended Opinion setting forth its conclusions with respect to the claim construction issues (the “Markman Opinion”). Par moved for reconsideration of the Markman Opinion or, alternatively, for relief from the scheduling order to permit supplemental discovery. Roxane moved for reconsideration and clarification of the Markman Opinion and accompanying order. Roxane moved for summary judgment of noninfringement of both patents. On September 8, 2006 the court granted Par’s motion for reconsideration of the Markman Opinion and accompanying order and substituted as the definition of “stable flocculated suspension” the following: “a suspension that resists caking and is redispersible after settling, wherein individual insoluble particles form open network aggregates. Such suspensions are not limited to suspensions disclosed as preferred embodiments

of the '318 and '320 patents". The court also denied Roxane's motion for summary judgment of noninfringement of the '318 and '320 patents.

There remain pending Roxane's motions for summary judgment that the '318 and '320 patents are invalid for lack of enablement and for summary judgment that the '320 patent is invalid for obviousness and/or indefiniteness.

### **I. Background**

The '318 and '320 patents are directed to stable flocculated suspensions of megestrol acetate and methods for using and manufacturing such suspensions. Megestrol acetate is used to stimulate the appetite of patients suffering severe weight loss, such as patients suffering from advanced AIDS or undergoing chemotherapy. Megestrol acetate can be administered as a capsule or tablet. High doses are required to achieve significant appetite stimulation. It is difficult for patients, particularly those suffering from loss of appetite, to swallow large numbers of capsules or tablets. Providing megestrol acetate in liquid form enables a patient to get an effective dose comfortably.

Problems were encountered in formulating megestrol acetate in liquid form. Megestrol acetate is highly insoluble in water and therefore particles of the drug will sink toward the bottom of the container, rendering doses that may be too high or too low to be safe and effective. The preferred dosage form is a liquid suspension whereby the solid megestrol acetate particles can be resuspended relatively evenly in liquid.

Megestrol acetate presents a particular problem in this regard. Because the surface energy of megestrol acetate particles is lower when they contact one another than when they contact water, megestrol acetate particles form a hard cake when they settle that cannot be easily

resuspended by shaking. In addition, particles of megestrol acetate entrap air on their surface making it particularly difficult to mix the particles into water. A surface agent, known as a surfactant, is required in the formulation to reduce interfacial surface tension of the particles and allow them to be mixed into the suspension.

It is an object of the '318 and '320 patents "to provide a liquid composition of megestrol acetate in the form of a flocculated suspension" ('318 patent; col. 3, 12-4; '320 patent, col. 3, ll. 20-22). The claimed discovery was that such a suspension could be formed by using any surfactant in combination with one or more wetting agents, specifically polyethylene glycol, propylene glycol, glycerol and sorbitol.

Roxane is alleged to have infringed independent claims 19 and 41 and dependent claims 20, 25, 26, 27, 31, 32, 34, 35, 42, 47, 48, 49 and 53 of the '318 patent and independent claim 1 and dependent claims 2, 6, and 7 of the '320 patent. The asserted claims of the '318 patent cover stable flocculated suspension of megestrol acetate where megestrol acetate is combined with one or more of the wetting agents referred to above and a surfactant. Independent claim 19 of the '318 patent recites:

An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising:

- (a) megestrol acetate;
- (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and
- (c) a surfactant

Independent claim 41 recites:

An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising:

- (a) megestrol acetate;
- (b) at least one compound selected from the group consisting of propylene glycol, glycerol, and sorbitol; and
- (c) a surfactant.

The asserted claims of the ‘320 patent are directed to methods of manufacturing megestrol acetate suspensions. Independent claim 1 recites:

A method of preparing an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising:

forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

## **II. Prosecution of the ‘318, ‘320 Patents**

The development of Par’s megestrol acetate product and the prosecution of the ‘318 and ‘320 patents and related patents has a lengthy history that bears significantly upon the enablement issue.

A. The Atzinger Patent: Neither Par nor Roxane was the first company to develop and market such a product. Bristol-Myers Squibb (“BMS”) first developed such a product and began marketing it in the United States, upon approval in 1993, under the name Megace. Both Par’s and Roxane’s products are generic versions of Megace in that both were approved as generic versions of Megace under the Hatch-Waxman provisions of the Food, Drug and Cosmetics Act, 21 U.S.C. §355(j).

Like Par's product, BMS's Megace is formulated in the type of suspension known as a flocculated suspension. As previously described in earlier opinions in this case, in a flocculated suspension the megestrol acetate, instead of sinking to form a hard cake, assembles in loose aggregates known as floccules, as the megestrol acetate settles under the influence of gravity. As these megestrol acetate floccules continue to settle over time the settling floccules stack up on each other to form a sediment with an open, scaffold - like structure that entraps the liquid. This scaffold like structure prevents the megestrol acetate from caking into a hard cake at the bottom of the container. Because a hard cake does not form, upon shaking, the megestrol acetate is easily redispersed throughout the liquid such that a uniform dosage can be dispensed.

Flocculated suspensions are formed by adding additional ingredients, excipients, to the water to aid in dispersing the insoluble drug particles throughout the water and preventing the drug particles from agglomerating together to form a hard cake. Prior to BMS's formulation of Megace it was known that surfactants,<sup>1</sup> wetting agents<sup>2</sup> and other excipients were used to formulate flocculated suspensions. The art lay in selecting the right excipients in the right amounts to achieve a flocculated suspension of a particular insoluble compound.

BMS's Megace flocculated suspension product uses a surfactant, polysorbate, a wetting agent, polyethylene glycol and several other excipients. BMS had obtained a patent which

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<sup>1</sup> A "surfactant" is any compound that reduces surface tension when dissolved in water or water solutions, or that reduces interfacial tension between two liquids, or between a liquid and a solid. There are three categories of surface-active agents: detergents, wetting agents, and emulsifiers; all use the same basic chemical mechanism and differ chiefly in the nature of the surfaces involved. (Hawley's Condensed Chemical Dictionary, 14<sup>th</sup> Ed. (2001), p. 1061).

<sup>2</sup> A "wetting agent" is a surface-active agent that, when added to water, causes it to penetrate more easily into, or to spread over the surface of, another material by reducing the surface tension of the water. Soaps, alcohols, and fatty acids are examples.

claimed the specific surfactant and wetting agent in its Megace product, U.S. Patent No. 5,338,732 to Atzinger et al. (“Atzinger” or “‘732 patent”). The only prior art reference in the ‘318 and ‘320 patents was Atzinger, discussed at some length in Par’s specification (‘318 Col. 1, l. 64-Col. 2, l. 19; ‘320 patent Col. 2, ll. 8-33). Atzinger taught that stable suspensions of megestrol acetate could be created only using formulations which limited the range of the surfactant polysorbate 80 to between 0.005% and 0.02% weight/volume and the wetting agent, polyethylene glycol, (PEG) 1450 to concentrations of between 5% and 30% weight/volume. Polysorbate 80 concentrations outside the specified range resulted either in the megestrol acetate not “wetting” (i.e., mix in water if too low), or if too high caking. Suspensions using lower than specified concentrations of PEG “required additional efforts to wet the drug and were found undesirable in that there was a small residual percentage of the drug in a dry state . . . which floated on the surface of the liquid.” (‘732 patent, col. 4, ll. 9-15).

It is Par’s claim that “[t]he inventors of the ‘318 and ‘320 patents discovered that stable flocculated suspensions of megestrol acetate could be formed using a much wider range of ingredients and concentrations than shown or suggested by Atzinger. See [‘318 patent,] col. 3, ll. 30-35; [‘320 patent] col. 3, ll. 52-56. They found that any surfactant could form such a suspension in the presence of one or more of the wetting agents, PEG, propylene glycol, glycerol and sorbitol, See [‘318 patent,] col. 4, ll. 5-10; [‘320 patent] col. 4, ll. 30-36” (Par’s Brief in Opposition at p. 3).

When Par decided to market a generic version of BMS Megace in about 1996 it recognized that it “need[ed] to formulate a product that (a) does not violate [Atzinger], (b) meets bioequivalence requirements, and (c) is flocculated and stable (i.e. no caking) over a period of 24

months.” Par had previously developed a formulation “that closely mimicked the innovator product. The only exception was to use polysorbate 80 at 0.05% instead of 0.01%. This change from the innovator formulation led to a non-bioequivalent product. The reason ascribed was lack of flocculation due to presence of excess polysorbate 80 in the formulation” (Product Development Report 9/30/99 at p. 3).

Atzinger provided the guidance for Par to proceed to develop a bioequivalent product:

Hence the use of a surfactant and wetting agent are required to provide a suspension and maintain physical stability. The flocculated suspension of megestrol acetate of this invention requires that megestrol acetate be micronized so that 90% of the weight of particles is below 20 microns and the mass median diameter is between 3.0 and 10 microns, and that the micronized particles are dispersed in water with surfactant or wetting agent such as polysorbate 80 and polyethylene glycol 1450 which are present to reduce interfacial tension between the particle, entrapped gas and water.

Surfactants having properties similar to polysorbate 80 can also be used.

Atzinger, col. 3, ll. 11-22 and 62-63).

Par proceeded to formulate its product using another surfactant known for use in flocculated suspensions, docusate sodium, and another wetting agent known for use in flocculated suspensions, glycerin. When Par filed its application for FDA approval to sell its generic product in 1999, BMS sued Par for patent infringement. Par prevailed on a summary judgment of non-infringement, and that decision was affirmed on appeal. Bristol-Myers Squibb Co. v. Par Pharmaceuticals, Inc., 2001 WL 823883 (Fed. Cir. 2001).

Thus, following the general approach prescribed in Atzinger and striking closely to the Atzinger components and quantities, Par was able, by trial and error, to select from the large number of surfactants and wetting agents a combination that produced a stable flocculated

suspension of megestrol acetate. As discussed below, however, it has secured the issuance of two patents the claims of which are so broad that they prevent anyone else from pursuing the same trial and error method to produce a stable flocculated suspension of megestrol acetate.

B. The '241 Application: On April 20, 1998 Par filed its patent application Serial No. 9/063,241 ("the '241 Application"). In the '241 Application Par noted Atzinger's admonition that "megestrol acetate flocculated suspensions are unique because what would otherwise be predictable based on prior art teachings does not apply when the drug is megestrol acetate," and that "the amount and type of surfactants are particularly critical in providing a stable floc." ('241 Application pp. 2, 6).

Par included three working examples of flocculated suspensions in the '241 Application, one of which used the exact same surfactant that BMS used, polysorbate 80, with two different wetting agents, glycerol and sorbitol, and two of which used another surfactant, docusate sodium, one with the same wetting agent that BMS has used, polyethylene glycol, and two with two other wetting agents, glycerol and sorbitol. The other ingredients in Par's examples were copied from BMS's Atzinger Patent and were used in almost identical quantities. In the '241 Application there were listed hundreds of compounds that were offered as possible surfactants to formulate flocculated suspensions of megestrol acetate ('241 Application at p. 6, l. 33 to p. 7, l. 27). Except for the surfactant docusate sodium, no guidance was offered as to the quantities of those surfactants to use, the identities or quantities of the wetting agents to use with those surfactants, or the identities or quantities of other excipients to use with the surfactants. In the case of the one exception, docusate sodium, a range of 0.0001 to 0.03% is suggested.

During its period of experimentation Par failed to formulate stable flocculated

suspensions with a number of surfactants, but in its '241 Application Par sought to patent any flocculated suspension of megestrol acetate made with any surfactant in combination with one or more of four wetting agents, including the wetting agent BMS had recommended in Atzinger, polyethylene glycol. Independent claim 1 in Par's '241 Application read:

An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: (a) megestrol acetate; (b) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

'241 Application, p. 14

The proviso at the end of the claim excluding the simultaneous presence of polysorbate (a surfactant) and polyethylene glycol (a wetting agent) served to exclude the specific combination of surfactant and wetting agent recommended in BMS's Atzinger patent. Thus Par attempted to patent everything (including combinations it knew didn't work) except the specific combination of wetting agent and surfactant in BMS's preferred formulation.

Examiner Kulkosky, the first patent examiner to review Par's patent application, rejected the claims for going beyond anything Par had invented. In an Office Action dated March 12, 1999 (March 1999 Office Action), in addition to rejecting all of Par's claims under 35 U.S.C. § 103(a) as obvious in view of Atzinger, Examiner Kulkosky also rejected the claims under 35 U.S.C. § 112, second paragraph, for failing to particularly point out the invention:

Also, the suspension stability demonstrated for the specific examples of the specification may depend upon the exact formulation of same. If the exact formula is critical, then all claims must be limited to same.

Claims 1-22 are rejected under 35 U.S.C. § 112 para. 2.

The claims define compositions which are not limited to improved suspension

stability, whereas the specification indicates that this property is critical.

The claims do not define a composition which possesses improved stability as due to required ingredients in definite amounts.

(Id., p. 3).

In a response to the March 1999 Office Action, filed on June 11, 1999 (June 1999 Response), Par declined to amend its patent claims and instead argued against Examiner Kulkosky's rejection. Among other things, Par stressed the unpredictability of successfully formulating a stable flocculated suspension of megestrol acetate once any change was made in the type or amount of any ingredient, including the surfactant or wetting agent:

In addition, based on the uncertainty of results once any modification in types of ingredients or amounts is made, as discussed in the prior art including Atzinger et al. [sic, et al.] (see also column 4, lines -22), a person skilled in the art would not have any reasonable expectation of success in maintaining a stable flocculated suspension of megestrol acetate once a change in the type or amount of surfactant or wetting agent is made. In fact, all of the working examples in Atzinger et al. use polysorbate 80 at concentrations between 0.005 to 0.03% w/v in conjunction with polyethylene glycol at concentrations greater than 5% w/v. As indicated hereinabove, the present invention relates to the surprising finding that it is possible to formulate a stable flocculated suspension of megestrol acetate using a combination of a surfactant with a wetting agent selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol.

(Id. p. 2) (emphasis added).

In a final Office Action dated September 3, 1999 (September 1999 Final Office Action), Examiner Kulkosky rejected Par's arguments and continued the rejection of all claims, both on grounds of obviousness under 35 U.S.C. § 103(a) and for lack of definiteness under 35 U.S.C. § 112, second paragraph. In the September 1999 Final Office Action, Examiner Kulkosky again pointed out that the claims were not limited to the formulations that Par had shown would work:

Claims 1-22 are rejected under 35 U.S.C. 112, paragraph 2.

The claims comprise formulas whose stability is not of a definite range. Example 4 at page 13 of the specification indicate [sic, indicates] stability results, whereas the compositions of the claims may not possess the critical property.

(Id. p. 3).

On September 29, 1999 Par filed a response to the September 1999 Final Office Action with the PTO (September 1999 Response), in which it amended claim 1 by limiting it to specific ranges of quantities of all claimed ingredients and adding a limitation specifying the stability of the claimed suspensions. The amended claim read as follows (amendments underlined):

1. (Amended) An oral pharmaceutical composition in the form of a stable flocculated suspension in water capable of being redispersed after being allowed to settle at 40° C and 75% relative humidity for a period of three months, said composition comprising:
  - (a) about 10 to 100 mg per ml micronized megestrol acetate;
  - (b) about 10 top 40% by weight of at least one compound selected from the group consisting o polyethylene glycol, propylene glycol, glycerol, and sorbitol; and
  - (c) about 0.0001 to 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

(Id. p. 1).

In Par's remarks accompanying its September 1999 Response, Par stated:

The Examiner rejected claims 1-22 under 35 U.S.C. § 103 as allegedly unpatentable over U.S. Patent No. 5,338,732 to Atzinger et al. (Atzinger '732)

In response, applicants have hereinabove amended claim 1 to indicate that the megestrol is micronized and to specify the range of concentrations of each of the three ingredients in the claimed composition. In addition, claim 1 was also amended to indicate that a stable flocculated suspension in water is a suspension capable of being redispersed after being allowed to settle at 40°C and 75% relative humidity for a period of three months.

The stability of the suspension of the present invention is described on page 13 of the specification as the ability to be redispersed after being allowed to settle at 40°C and 75% relative humidity for a period of three months.

(Id. p. 2).

Only after Par narrowed its broad claims in this way did Examiner Kulkosky issue a notice of allowance for claim 1 and its dependent claims, and the ‘241 Application issued on February 22, 2000 as U.S. Patent No. 6,028,065 (“the ‘065 patent”). Par has not sued Roxane for infringement of the ‘065 patent.

Par’s ‘356 Patent: On October 12, 1999, shortly after filing the September 1999 Response in the ‘241 Application, Par filed application Serial No. 09/416,841 (“the ‘841 Application”) as a continuation of the ‘241 Application. The only claim Par submitted for examination in the ‘841 Application was to a method of treating a neoplastic condition by administering the composition of claim 1 as issued in the ‘065 patent. (October 1999 Preliminary Amendment).

On June 21, 2000, Examiner Kulkosky, the same examiner who had reviewed the ‘241 Application, issued an Office Action in the ‘841 Application (June 2000 Office Action), rejecting the pending claim under 35 U.S.C. § 112, first paragraph:

“The composition of claim 23 is not supported by enabling disclosure since the ‘surfactant’ of same would required undue experimentation to choose over all the possible ranges of ingredients and species of same possible for the formula.” Surfactants used in the formulas of the specification are examples are [sic, of] the types which can be counted upon to the [sic, be] useful to yield the required redispersibility. It appears that a required combination of surfactant species is necessary (see discussion at pages 6-8 of the specification). It is suggested that the claims should be limited to contain surfactants of definite chemical formula, such as those of the working examples.

(Id., p. 2) (emphasis added).

Par filed its response on September 20, 2000 (September 2000 Response) in which it confirmed a telephone interview with Examiner Kulkosky during which Par had pointed out that the method claim in the ‘841 Application relied on the exact formulation that Examiner

Kulkosky had already allowed in the ‘065 patent. (Id., p. 1). Examiner Kulkosky issued a notice of allowance on September 22, 2000, and the ‘841 Application issued as U.S. Patent No. 6,268,356 on July 31, 2001 (“the ‘356 patent”). Par has not sued Roxane for infringement of the ‘356 patent.

**D. Par’s Pursuit of Broad Claims in the ‘318 Patent:** Shortly after the notice of allowance in the ‘841 Application, on January 9, 2001, Par filed application Serial No. 09/757,261 (“the ‘261 Application”) as a continuation of the ‘841 Application. In an accompanying preliminary amendment (January 2001 Preliminary Amendment), Par amended the ‘261 Application to include only method claims. The ‘261 Application was assigned by the PTO to a different art unit than the ‘241 and ‘841 Applications: 1616 instead of 1615, and to a different examiner, Konata George (‘261 Application Confirmation No. 6642).

Examiner George performed a prior art search on November 29, 2001 (File Wrapper Search Notes), and on December 18, 2001, issued an Office Action rejecting all pending claims on obviousness-type double patenting grounds over Par’s ‘065 and ‘356 patents (December 2001 Office Action).

On November 15, 2001, i.e., prior to receiving the December 2001 Office Action, Par submitted a further Preliminary Amendment (November 2001 Second Preliminary Amendment), adding new composition claims, including new independent claim 41 (which corresponds to claim 19 in the ‘318 Patent) and new independent claim 63 (which corresponds to claim 41 in the ‘318 Patent) of the same broad scope that Examiner Kulkosky had rejected in the earlier ‘241 Application, i.e., these claims did not recite any ingredient quantities or stability limitations:

41. An oral pharmaceutical composition in the form of a stable flocculated

suspension in water comprising: (a) megestrol acetate; (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) a surfactant.

63. An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: (a) megestrol acetate; (b) at least one compound selected from the group consisting of propylene glycol, glycerol, and sorbitol; and (c) a surfactant.

(Id. pp. 4, 7).

In its remarks accompanying the December 2001 Second Preliminary Amendment, Par told the PTO that “A series of new claims covering subject matter disclosed but not previously specifically claimed in this application or in the parent applications/patents is being presented for consideration by the Examiner.” (Id. p. 3).

Although Par represented to the PTO that the new independent claims 41 and 63 covered subject matter not previously claimed “in the patent applications/patents,” new independent claims 41 and 63 claimed the same subject matter, phrased in a slightly different way, that Par had claimed and Examiner Kulkosky had rejected in the ‘241 Application. Original claim 1 in the ‘241 Application had claimed “An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising (a) megestrol acetate, (b) a surfactant, and (c) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, wherein polysorbate and polyethylene glycol are not simultaneously present.” (‘241 Application, p. 14). New Claim 41 in the ‘261 Application is identical, except that it requires two compounds from the group of wetting agents consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol rather than “at least one”, and drops the proviso that polysorbate and polyethylene glycol are not simultaneously present; and new claim 63 is also

identical except that it excluded polyethylene glycol from the group of wetting agents. Neither new independent claim contained any of the limitations as to the amounts of the ingredients or as to stability that Examiner Kulkosky had required Par to add to claim 1 in the '241 Application to obtain allowance.

In an Office Action dated February 22, 2005, Examiner George acknowledge receipt of the Second Preliminary Amendment on January 8, 2002, i.e., after the December 2001 Office Action had already issued, and requested a response to that Office Action. (February 2002 Office Action).

On March 8, 2002, Par submitted a terminal disclaimer to overcome the double patenting rejection in the December 2001 Office Action, and on April 9, 2002, Examiner George issued a Notice of Allowance of all pending claims and an Examiner's Statement of Reasons for Allowance (First Statement of Reasons):

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious method [sic] of treating a neoplastic condition comprising administering to a subject suffering from said condition an oral pharmaceutical composition in the form of a stable flocculated suspension in water capable of being redispersed after being allowed to settle at 40°C and 75% relative humidity for a period of three months, said composition comprising: (a) micronized megestrol acetate; (b) about 10 to 40% by weight of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) about 0.0001 to 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

(Id., p. 2).

On April 26, 2002, Par filed with the PTO a request for expedited patent issuance based on the April 9 Notice of Allowance. Par recognized that Examiner George misunderstood the

scope of the claims in his First Statement of Reasons, because the Examiner had made reference to limitations that were not present in broad independent claims 41 and 63 which had been added in the Second Preliminary Amendment. Accordingly, when Par requested expedited issuance it also submitted a document captioned Comments on Statement of Reasons for Allowance in which Par pointed out that Examiner George had allowed numerous claims broader in scope than the claim whose language Examiner George quoted in his First Statement of Reasons, for example, new claim 63. (Par's April 2002 Comments). Before Examiner George could respond to Par's comments, the '261 Application was withdrawn from issuance because of an interference between the '261 Application and another party's patent application.

After the interference was resolved, Examiner George issued a new Notice of Allowance on October 23, 2002 (October 2002 Notice of Allowance), but failed to address Par's April 2002 Comments. On November 27, 2002, Par submitted another document titled Comments on Statement for Reasons of Allowance, raising the same issues it first raised in its April 2002 Comments, and confirming a telephone interview with Examiner George in which he agreed to issue a Supplemental Notice of Allowance clarifying the reasons for allowance. (Par's November 2002 Comments). Examiner George issued the Supplemental Notice of Allowability and a Statement of Reasons for Allowance ("Supplemental Statement of Reasons") on March 24, 2003, in which he stated:

In addition to the reasons given in the previous office action (paper No. 14) the claims are allowable because the prior art does not teach, disclose nor make obvious an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: megestrol acetate, at least one compound selected from the group consisting of polyethylene [sic, polyethylene glycol,] propylene glycol, glycerol, and sorbitol; and a surfactant.

(Supplemental Statement of Reasons, p. 2).

At no time during the extensive prosecution of the ‘261 Application did Par advise Examiner George that claims of substantially the same scope as claims 41 and 63 (claims 19 and 41 of the ‘318 Patent as issued) had been rejected by Examiner Kulkosky, both for obviousness and overbreadth.

The ‘261 Application issued as the ‘318 Patent on July 15, 2003, and Par sued Roxane for infringement that same day.

E. The ‘320 Patent: Just after Par requested expedited issuance of the ‘261 Application, Par filed application Serial No. 10/136,823 (“the ‘823 Application”) as a division of the ‘261 Application. The ‘823 Application was accompanied by a Preliminary Amendment limited to claims directed to methods of making stable flocculated suspensions of megestrol acetate. (April 2002 Preliminary Amendment). The only independent claim read as follows:

A method of preparing an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

(Id., p. 4).

Examiner George’s first communication in the ‘823 Application was an allowance issued on December 13, 2002. (December 2002 Notice of Allowability). In the accompanying Statement of Reasons for Allowance, Examiner George stated:

The claims are allowable over the prior art because the prior art does not teach, disclose nor make obvious a method of preparing an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising: forming a solution by combining water with (a) at least one compound selected

from the group consisting of polyethylene glycol, propylene glycol, glycerol or sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

(Id. p. 2).

As with the '318 patent, at no time during prosecution of the '320 Patent did Par advise Examiner George or Examiner Kulkosky's rejection for obviousness and overbreadth of Par's broad claims in the '241 Application.

The '823 Application issued as the '320 Patent on July 15, 2003, and Par sued Roxane for infringement of the '320 Patent that same day.

### **III. Discussion**

A. Summary Judgment Standards: Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The threshold inquiry is whether "there are any genuine factual issues that can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986) (noting that no issue for trial exists unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict in its favor). In deciding whether triable issues of fact exist, the Court must view the underlying facts and draw all reasonable inferences in favor of the nonmoving party. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

A patent is presumed valid. 35 U.S.C. § 282. As a consequence, the patent challenger must prove, by clear and convincing evidence that the patent is invalid. Ryko Mfg. Co. v. Nu-  
Star, Inc., 950 F. 2d 714, 716 (Fed. Cir. 1991). At the summary judgment stage of a proceeding all evidence of invalidity must be viewed in a light most favorable to the non-moving party and all evidentiary doubts must be resolved in the non-moving party's favor. Johns Hopkins Univ. v. Cellpro, Inc., 152 F. 3d 1342, 1359 (Fed. Cir. 1998); Eli Lilly & Co. v. Barr Labs., 251 F. 3d 955, 962 (Fed. Cir. 2001).

B. Enablement: Whether a claim is enabled under 35 U.S.C. § 112, first paragraph is a question of law based upon underlying factual findings. See PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996). To be enabling, a specification must describe the invention sufficiently to enable one of skill in the art to practice the claimed invention without undue experimentation. See Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F. 2d 1569, 1576 (Fed. Cir. 1984) (emphasis added). The specification is not required to teach every possible embodiment that falls within the scope of a claim in order to be enabling. Amgen Inc., 314 F.3d at 1336-3. “Enablement looks to the placing of subject matter of the claims generally in the possession of the public.” Spectra-physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532 (Fed. Cir. 1987); In re Fisher, 57 C.C.P.A. 1099, 1108 (C.C.P.A. 1970). See Phillips v. AWH, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (reaffirming that the scope of the invention is limited by the claims, not the specification).

The measure of undue experimentation is made at “the time the application was filed” from the perspective of a person of ordinary skill in the field of the invention. Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F. 3d 1338, 1345 (Fed. Cir. 2000). That some experimentation

is necessary does not preclude enablement - "the key word is undue not experimentation." *In re Wands*, 858 F.2d 731, 737-738 (Fed. Cir. 1988).

Par contends that the inventors of the '318 and '320 patents discovered that stable flocculated suspension of megestrol acetate could be formed using a much wider range of ingredients and concentrations than shown or suggested by Atzinger and that, in particular, they found that any surfactant could form such a suspension in the presence of one or more of the wetting agents, PEG, propylene glycol, glycerol and sorbitol. The asserted independent claims of the two suit patents, claims 19 and 41 of the '318 patent and claim 1 of the '320 patent, are for stable flocculated suspensions of megestrol acetate ('318 patent) and methods of making such suspensions ('320 patent). Both patents derive from a common ancestor, the '241 Application, and so have the same common specification. As written the claims encompass every possible megestrol acetate flocculated suspension made with any surfactant and one or more of the listed wetting agents, with the exception of the specific combination of surfactant and wetting agent recommended in Atzinger - polysorbate and polyethylene glycol.

Thus Par's claims have an extraordinarily broad scope. In consequence the scope of the enablement must be commensurate with scope of the claims. A general enablement rejection is appropriate when the written description does not enable any subject matter within the scope of the claim, such that the specification does not teach how to make or use the invention. That is not the case here because, as Par points out, the specification contains three working examples that explain how to prepare stable flocculated suspensions of megestrol acetate using the short-chain ionic surfactant docusate sodium as well as the long-chain surfactant polysorbate 80. Further, during its work on megestrol acetate suspensions Par tested other formulations using

other ionic and non-ionic surfactants.

However, under 35 U.S.C. § 112, the amount of supporting disclosure required to enable the full scope of a claim will depend on the claim's breadth and the degree of predictability in the art. Enzo Biochem, Inc. v. Calgene, Inc., 188 F. 3d 1362, 1374 n. 10 (Fed. Cir. 1999). Claims which encompass significant numbers of inoperative embodiments are not enabled if the specification does not identify which of many possibilities are operative, and undue experimentation is required to determine the operative embodiments, Atlas Powder Co. v. E.L. du Port De Nemours & Co., 750 F. 2d 1569, 1576-77 (Fed. Cir. 1984). The person of ordinary skill in the art must be able to make or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

In PPG Industries, the Federal Circuit highlighted the significance of unpredictability in evaluating the validity of broad claims:

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. . . . Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation . . . the experimentation must not be unduly extensive.

PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1564, (Fed. Cir. 1996) (citations omitted). See also, *In re Wands*, 858 F. 2d 731 (Fed. Cir. 1988); *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993) ("[T]his court discerns no error in the Board's conclusion of nonenablement. Goodman's specification does not enable one skilled in biotechnology in 1985 to practice the method for all 'plant cells' as application claims 1-9 require. The record, especially Goodman's

own article, shows the need for extensive experimentation to practice the claimed method for just a few plants, let alone all plant cells as broadly claimed in the application.”)

Par complains that “[a] full third of [Roxane’s] brief is devoted to re-hashing its inequitable conduct arguments, rather than discussing the facts or law pertinent to enablement.” (Par’s Brief in Opposition at p. 1). Of course, there are factual issues relating to the defense of inequitable conduct, but Par’s representations and conduct during the course of its prosecution of its various applications provide evidence critical to the issue of enablement. That evidence and the other evidence in the record establish as a matter of law that the ‘318 and ‘320 patents are not enabled to the full scope of their claims. AK Steel Corp. v. Sollee, 344 F.3d 1234 (Fed. Cir. 2003).

The claims encompass every possible megestrol acetate flocculated suspension made with any surfactant and one or more of the listed wetting agents, with the exception of the combination that Atzinger recommended. Par’s common specification fails to provide an enabling disclosure of similar scope. Par itself in its arguments to the PTO during prosecution insisted on the criticality of selecting the right ingredients and quantities and the unpredictability of achieving a stable flocculated suspension once any change is made in the types or amounts of ingredients.

Par’s common specification states:

The surfactants in a stable flocculated suspension need to be selected carefully and be used within a critical concentration range because even minor changes can have an effect on the properties of such a stable formulation. This is particularly true for megestrol acetate because predictability based on prior art teachings does not apply in this case, as noted hereinabove.

(‘318 Patent, col. 3, l. 66 to col. 4, l. 5; ‘320 Patent, col. 4, ll. 23-29).

[B]ased on the uncertainty of results once any modification in types of ingredients or amounts is made, as discussed in the prior art including Atzinger et al. [sic, et al.] (see also column 4, lines 1-22), a person skilled in the art would not have any reasonable expectation of success in maintaining a stable flocculated suspension of megestrol acetate once a change in the type or amount of surfactant or wetting agent is made.

(June 1999 Response, p. 2). The deposition testimony of Dr. James Chao, one of the named inventors of the suit patents, is consistent:

Q. "And then you go . . . there's a sentence . . . the sentence right after that, I'm sorry, the sentence directly after that that says, this is particularly, it starts on line 24? Do you see that"?

A. "Yeah".

Q. "And could you read the sentence into the record"?

A. "This is particularly true for megestrol acetate because predictability based on prior arts [sic] technique . . . teachings does not apply in this case, as noted hereinabove".

Q. "Okay. And do you . . . did you agree with that statement at the time that this was written"?

A. "Yeah. Prior . . . prior arts didn't teach us. Right. That's right".

Q. "But do you agree with the statement that . . . that predictability based on the prior art doesn't apply for megestrol"?

A. "I agree. No".

Q. "You don't agree or you do agree"?

A. "No, no, I say I agree".

Q. "Okay".

A. "You . . . you won't . . . you cannot predict".

Q. "So what is it that you can't predict? Whether you're going to get a stable flocculated suspension"?

THE WITNESS: "I can predict only after we study, experimented".

Q. "And after you experimented, what could you predict"?

A. "I can predict the range. Say I can use this concentration, other concentration either one is workable".

Q. "Okay".

A. "That's the prediction"

Q. Okay. So the prediction, for example, for docusate sodium based on the work you did, you know what the range is of docusate sodium".

A. "That's right".

Q. "Once you did that work, does that enable you to predict what the concentration range should be for another surfactant"?

A. "No".

(1/5/05 Chao Dep. Tr., p. 278, line 4 to p. 280, line 2).

In the BMS v. Par litigation, before Par had obtained the broad claims asserted in this action, Par's technical expert, Dr. Stanley Hem, opined that "Formulating a flocculated suspension is, in my view, one of the most delicate formulation efforts in terms of balancing the excipients, and it is also very difficult to predict in terms of what its properties will be or what the effect of different excipients will be. There is no known method in the art to predict whether

a change in inactive ingredients will produce a stable suspension.” (Expert Report of Dr. Stanley Hem in BMS v. Par, pp. 4-5 (emphasis added).

Par’s technical expert in this case, Dr. Alexander Klibanov, says that megestrol acetate is sufficiently unique as a compound that prior art references teaching how to wet other insoluble compounds provide absolutely no guidance with regard to wetting megestrol acetate. (Expert Report of Dr. Alexander klibanov, pp. 10-11). According to Dr. Klibanov, a prior art treatise teaching general principles for formulating suspensions is insufficient to “set up the lengthy series of experiments needed to demonstrate that megestrol acetate . . . can be wet with any surfactant in the right concentration.” (Id., p. 16) (emphasis added). Independent claims 19 and 41 of the ‘318 Patent and claim 1 of the ‘320 Patent contain no limitations concerning the amounts of any of the required ingredients. The common specification teaches only three working examples of the claimed inventions, one with the surfactant Atzinger used, polysorbate, and two with docusate sodium. Par’s claims encompass literally hundreds of compounds, apart from polysorbate (‘318 Patent, col. 4, ll. 11-36; ‘320 Patent, col. 4, ll. 37-65), alleged to be suitable as the surfactant in Par’s broad claims. The specification of the suit patents shows only one new surfactant which works - - docusate sodium.

Par was unable to formulate stable flocculated suspensions with other surfactants. According to Robert Femia, a named inventor of the suit patents, Par tested only a handful of surfactants, namely tergitol, sodium lauryl sulphate (“SLS”), cetyl trimethyl ammonium bromide (“CTAB”), BRIJ® 35 and MYRJ®, docusate sodium, and polysorbate (Femia Dep. Tr. in BMS v. Par, pp. 142, line 9 to 143, line 16). Of these seven surfactants, a modest number of the hundreds within the scope of the claims, Femia testified that Par was unable to formulate stable

flocculated suspension of megestrol acetate with at least four of them - - SLS, BRIJ® 35, CTAB and MYRJ® - - and he did not recall the result of the experiments involving teritol. (Id., pp. 144, line 5 to 149, line 13). Par's internal records show that numerous formulations employing MYRJ were created, as well as several employing SLS. PA 009487-9492; PA 010205-208; PA 010293-302; PA 010305-310; PA 010314-319; PA 010323-325).

As for the success Par did have with its commercial product, in which the surfactant is docusate sodium, that came “[o]nly with much experimentation over the course of a number of months in 1997. . .” (6/8/05 Expert Report of Dr. Alexander Klibanov, p. 12). As Par argued to the Federal Circuit in BMS v. Par, Par's product resulted “. . . after long effort [to] design [] around the ‘732 patent . . .” (Par's Brief to the Federal Circuit in BMS v. Par, p. 15).

Par challenges Roxane's conclusion based on this and other evidence that a person of ordinary skill in formulating oral suspension dosage forms would have to perform an undue amount of experimentation to practice the full scope of the claimed inventions of the '318 and '320 patents. Par points to the three working examples provided in the specification which, among them use two surfactants, docusate sodium and polysorbate 80. The examples spell out the wetting agents and excipients used with the surfactants and, according to Par, “read in the context of the rest of the specification provide guidance for using both ionic and nonionic surfactants.” (Par's Opposition Brief at p. 4). Further, Par argues that during the course of its work on megestrol acetate suspensions it tested numerous formulations using a wide variety of ionic and nonionic surfactants and formed stable megestrol acetate suspensions using the surfactants polysorbate 80, docusate sodium, sodium lauryl sulphate, MYRJ (also known as poly oxyl 50 sterate), Tergitol (also known as Nonorynol - 9), BRIJ 35 (also known as

polyoxyethylene 23 lauryl ether) and cetyl trimethyl ammonium bromide (CTAB).

Par, however, misses the point at issue in this case. It is not that no subject matter within the claims is enabled, because some examples within the claims certainly are enabled. The point is that the specification does not enable the full scope of the claims as recited above. Claims 19 and 41 of the '318 patent and Claim 1 of the '320 broadly claim any surfactant, in any amount, in combination with any of the recited wetting agents. The specification recites a long list of "suitable" surfactants ('318 patent, col. 4, ll 11-36) and notes that they "need to be selected carefully and used within a critical concentration range because even minor changes can have an effect on properties of such a stable formulation. This is particularly true for megestrol acetate because predictability based on prior art teachings does not apply in this case, as noted herein-above." ('318 patent, col. 3, l. 66 to col. 4, l. 5).

The prosecution history, recounted in some detail above, confirms that the level of uncertainty in the prior art is high, an unpredictability that Par relied upon in its efforts to persuade the Patent Office that its claims were patentable.

Par contends that the testimony of Dr. Harry Brittain, Roxane's technical expert, that Par's claims are obvious in view of the prior art, is inconsistent with his opinion that the claims are not enabled. Dr. Brittain did not opine that it would have been obvious to change the type and/or amount of surfactant employed in Atzinger with the expectation of achieving a stable flocculated suspension. His opinion on obviousness was addressed to the wetting agents claimed by Par. According to him it would have been obvious to arrive at Par's invention by starting with Atzinger's flocculated suspension of megestrol acetate, which employs at specific concentrations, the surfactant polysorbate and the wetting agent polyethylene glycol, and then adding another

wetting agent, or replacing the polyethylene glycol with another wetting agent, while leaving the surfactant type and amount unchanged. This is not inconsistent with the proposition that the full scope of the asserted claims employing an surfactant in any concentration is not enabled because a person or ordinary skill in the art is not taught how to practice the full scope of the claim.

In its Opposition Brief Par argues that Roxane overstates the scope of the claims, failing to recognize that they are all directed to oral pharmaceutical compositions, and consequently the compositions must be suitable for consumption. Pharmaceutical formulators rely on compounds for which standards are adopted by the United States Pharmacopia and National Formulary (“USP-NF”), with reference to purity, identity, packaging, storage requirements, etc. At the time of Par’s invention the USP-NF listed only twenty-four surfactants termed “wetting and/or solubilizing agents,” at least two of which are not suitable for oral pharmaceutical suspensions. Par notes that at least ten of the twenty-two suitable surfactants have been shown to form stable megestrol acetate suspensions through Par’s experiments, or are identified by Atzinger, or are surfactants used by Morton Grove Pharmaceutical, Inc. and Roxane.

This attempt to narrow the scope of the claim must fail. Par asserted in the common specification and the prosecution history that “any” surfactant can be used and the specification contained a list encompassing hundreds of “suitable” surfactants. The claims do not delimit the surfactant that can be used.

During the claim construction proceedings in this case Par asserted that the claims in the patents in suit are not limited to commercially viable suspensions of megestrol acetate. It would follow that the claim term “surfactant” cannot be limited to surfactants that are commercially viable, i.e., approved for use in oral pharmaceutical compositions. Par’s position contradicts the

specification. The list of twenty-two surfactants it now submits as suitable for oral suspensions cannot be used to limit the much longer list of surfactants contained in the common specification. That list includes many surfactants that are not included in the list Par now provides. In its Opposition Brief (at pp. 13, et seq.) Par relies upon its own experiments employing the surfactants BRIJ 35 and CTAB to confirm that the claims are enabled, yet neither of those surfactants is included in Par's list of surfactants included within the claims language. Par's Product Development Report, upon which Par relies as evidence of successful experiments with formulations falling within the scope of the asserted claims includes experiments employing Tergitol, a surfactant that the Report itself states is not suitable for a commercial oral pharmaceutical composition.

On the basis of evidence that cannot be disputed, as a matter of law Par is not entitled to the broad claims it asserts in this action. The disclosure of the common specification does not teach a person of ordinary skill how to practice the full scope of the claims<sup>3</sup>.

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<sup>3</sup> None of the asserted dependent claims 20, 25, 32, 34, 35, 42, 47 or 53 in the '318 patent or claims 2 or 7 in the '320 patent add any limitations as to amounts of ingredients to use and the enablement analysis referring to independent claims 19 and 41 of the '318 patent and independent claim 1 of the '320 patent applies to them without further discussion.

Par also asserts dependent claims 26, 27 and 31 (depending from claim 19), and 48 and 49 (depending from claim 41) of the '318 patent and claim 6 (depending from claim 1) of the '320 patent. Each of these claims contains an additional limitation not found in the independent claims, limiting the quantities of all wetting agents from an infinitesimal amount "up to" either 25% 30% or 40% w/v of the claimed suspension. Par has explained, however, that "based on the uncertainty of results once any modification in types of ingredients or amounts is made . . . a person skilled in the art would not have any reasonable expectation of success in maintaining a stable flocculated suspension of megestrol acetate once a change in the type or amount of surfactant or wetting agent is made." (June 1999 Response, p. 2). Given this unpredictability, the paucity of working examples in the suit patents, and the lack of any limitations as to the type or amount of surfactant, the addition of these broad ranges for the amounts of the wetting agents does not enable a person of ordinary skill to practice the full scope of these claims without undue

#### **IV. Conclusion**

Roxane's motion for summary judgment that claims 19, 20, 25, 26, 27, 31, 32, 34, 35, 41, 42, 47, 48, 49 and 53 of the '318 patent and claims 1, 2, 6 and 7 of the '320 patent are invalid for failure to comply with the enablement requirements of 35 U.S.C. § 112. In light of this conclusion it is unnecessary to address Roxane's motion for summary judgment for invalidity of claims 1, 2, 6 and 7 of the '320 patent on the ground that the asserted claims are invalid under 35 U.S.C. § 103(a) as obvious from the prior art and on the ground that the asserted claims are invalid for indefiniteness under 35 U.S.C. § 112, second paragraph, for claiming the alleged invention by what it is not, rather than by claiming what the alleged invention is. That motion will be dismissed without prejudice, with the right of Roxane to have it restored to the calendar should this case be reinstated for any reason. The case will be dismissed. The court will enter an appropriate order.

Dated: November 8, 2006

/s/ **Dickinson R. Debevoise**  
DICKINSON R. DEBEVOISE  
U.S.S.D.J.

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experimentation.